भारतीय मानक
Indian Standard

IS 17353 : 2020

चिकित्सीय वस्त्रादि — दबाव वस्त्र — विशिष्टि

Medical Textiles — Pressure Garment — Specification

ICS 11.140; 59.080.01

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February 2020 **Price Group 3**

Technical Textiles for Medtech Application Sectional Committee, TXD 36

FOREWORD

This Indian Standard was adopted by the Bureau of Indian Standards, after the draft finalized by Technical Textiles for Medtech Applications Sectional Committee had been approved by the Textile Division Council.

Pressure garments are used as a *medical compression garment* to treat venous and lymphatic medical problems. The patient applications of these garments include prevention of blood pooling in the limbs that can clot and result in venous thrombosis or deep vein thrombosis. Venous thrombosis develops when a blood clot forms in the deep veins located near the skeletal parts of the body surrounded by muscle. The legs are a very common place for these clots to form, as well as the arms. Blood clots can also lead to pulmonary embolism, which is often fatal.

The extent of pressure created by a pressure garment is based on the garment construction, structural and physical properties of its material, size and shape of body part to which it is to be applied and the type of activity involved. Pressure garments are individually designed and manufactured for a particular part of the body and also depends upon the individual condition of to be treated body part. This standard does not specifies requirements for application specific pressure garments, such as crepe bandage, elasticated tubular bandage, orthopedic stockinet, graduated medical compression stockings and anti-embolic stockings, and are covered in separate Indian Standard (Crepe bandage : IS 4605, Elasticated tubular bandage : IS 16946, Orthopedic stockinet : IS 16302, Graduated medical compression stocking : IS 16467).

The composition of the Committee responsible for the formulation of this standard is given in Annex B.

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated, expressing the result of a test or analysis shall be rounded off in accordance with IS 2 : 1960 ‘Rules for rounding off numerical values (*revised*)’. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

MEDICAL TEXTILES — PRESSURE GARMENT — SPECIFICATION

1 SCOPE

1.1 This standard specifies the requirements for pressure garment intended for medical use.

1.2 This standard does not specifies requirement for application specific pressure garment, such as crepe bandage, elasticated tubular bandages, orthopedic stockinet, graduated medical compression stockings, anti-embolic stockings etc. , and are covered in separate Indian Standard.

2 REFERENCES

The standards listed in Annex A contain provisions, which through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated in Annex A.

3 TERMS AND DEFINITIONS

For the purpose of this standard, the following definitions shall apply:

3.1 Pressure Garment — Pressure garment are used as a *medical compression device* to treat venous and lymphatic medical problems.

3.2 Manufacturer — Natural or legal person with responsibility for the processing of raw material or inputs in any manner that results in the emergence of a new product having a distinct name, character and use.

4 MANUFACTURE

The pressure garment shall be made from suitable textile material that is not prohibited for use for the purpose under any applicable law /regulation in force so that the product made out of this meets the requirements specified in this standard. These can be manufactured in various sizes and shapes as per the buyer/user requirements.

5 REQUIREMENTS

5.1 Workmanship and Finish

The pressure garment shall be clean and free from substances liable to cause tendering during storage. The manufacture and preparation of the pressure garments shall be conducted under proper hygienic conditions.

5.2 Performance Requirements

The pressure garment shall conform to the requirements specified in Table 1.

Table 1 Requirements for Pressure Garment

(*Clause* 5.2)

Sl No.	Characteristic	Requirement	Method of Test, Ref to
(1)	(2)	(3)	(4)
i)	Stretch in cross direction on double layer with a load of 900 g per 2.5 cm, percent, *Min*	340	—
ii)	Regain in stretched layer in cross direction, percent, *Max*	80	—
iii)	Breaking strength of single layer kg per 2.5 cm, *Min*:		IS 1969 (Part 2)
	a) Machine direction	40	
	b) Cross direction	3	
iv)	Elongation at break kg per 2.5 cm, *Min*:		IS 1969 (Part 2)
	a) Machine direction	40	
	b) Cross direction	400	

6 PACKING

The pressure garment shall be packed securely so as to allow normal handling and transport without tearing and exposing the contents. Details of the packing shall be as agreed to between the buyer and the seller. Packaging of the product should be, such as to maintain the integrity of the product throughout its shelf life.

7 MARKING

7.1 Each pack of the pressure garment shall be legibly and indelibly marked with following information:

a) Name of the product;
b) Dimension /size of the product;
c) Manufacturer's name, initials or trademark, if any;
d) Month and year of manufacture, batch/lot number; and
e) Any other statutory requirement as required by the law in force.

7.2 BIS Certification Marking

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act*, 2016 and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark.

8 SAMPLING AND CRITERIA FOR CONFORMITY

8.1 Lot

All the pressure garments of the same material and dimensions produced under similar conditions of manufacture shall constitute a lot.

8.1.1 Each lot shall be tested separately for ascertaining the conformity of the lot.

8.1.2 The number of pressure garments to be selected from the lot shall depend on the size of the lot and shall be in accordance with column 2, 3 and 5 of Table 2.

8.1.3 These pressure garments shall be selected at random from the lot. For this purpose, reference may be made to IS 4905.

8.2 Number of Tests and Criteria for Conformity

8.2.1 All the pressure garments selected as per column 3 of Table 2 shall be examined for workmanship and finish (*see* **5.1**).

8.2.1.1 Any pressure garment failing in one or more of the above requirements shall be termed as defective. The lot shall be considered as conforming to the above requirements, if the total number of defectives found in the sample is less than or equal to the acceptance number given in column 4 of Table 2. Otherwise, the lot shall be rejected.

8.2.2 Out of the sample already found satisfactory according to **8.2.1.1**, a sub-sample as per column 5 of Table 2 shall be taken. This sub-sample shall be further tested for the remaining requirements.

8.2.3 The lot shall be considered as conforming to the requirements of the specification if the total number of defective products found in the sample (as per **8.2.2**) is less than, or equal to the acceptance number as given in column 6 of Table 2.

Table 2 Number of Pressure Garments to be Selected

(*Clauses* 8.1.2, 8.2.1 and 8.2.1.1)

Sl No.	**Lot Size**	**Non-Destructive Testing**		**Destructive Testing**	
		No. of Garments to be Selected	Acceptance Number	No. of Garments to be Selected	Acceptance Number
	N	n	a	n_1	a_1
(1)	(2)	(3)	(4)	(5)	(6)
i)	Up to 280	13[1]	1	8	0
ii)	281 to 500	20	2	8	0
iii)	501 to 1 200	32	3	13	0
iv)	1 201 to 3 200	50	5	13	0
v)	3 201 and above	80	7	20	1

[1] or lot size when less than 13.

ANNEX A

(*Clause* 2)

LIST OF REFERRED INDIAN STANDARDS

IS No.	*Title*
4905 : 2015	Random sampling and randomization procedures (*first revision*)
1969 (Part 2) : 2018/ ISO 13934-2 : 2014	Textiles — Tensile properties of fabrics: Part 2 Determination of maximum force and elongation at maximum force using the grab method

ANNEX B

(*Foreword*)

COMMITTEE COMPOSITION

Technical Textiles for Medtech Applications, TXD 36

Organization	*Representative(s)*
The South India Textile Research Association, Coimbatore	Dr Prakash Vasudevan (***Chairman***)
3 M India Limited, New Delhi	Shri Kulveen Singh Bali Ms Vandana Singh (*Alternate*)
All Indian Institute of Medical Sciences, New Delhi	Dr Vijaydeep Siddharth Dr Anoop Daga (*Alternate*)
Business Coordination House, New Delhi	Shri Sameer Gupta Smt Ritika Gupta (*Alternate*)
Cologenesis Healthcare Pvt Ltd, Salem	Shri R. Krishnakumar Shri K. Ramprasad (*Alternate*)
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Indian Council of Medical Research, New Delhi	Dr B. K. Singh
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Kamal Healthcare Pvt Limited, Tamilnadu	Shri S. Sankar Marimuthu
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Procter and Gamble Co, Mumbai	Shri Prashant Jadhav Shri Sivakumar (*Alternate*)
PGIMER, Chandigarh	Shri Pankaj Arora

Organization	*Representative(s)*
Surgicotfab Textile Pvt Ltd, Ahmedabad	SHRI PARESH PATEL
South India Textile Research Association, Coimbatore	SHRI KETAN KUMAR SHRI T. SURESHRAM (*Alternate*)
Textiles Committee, Mumbai	SHRI KARTIKEYAN DHANDA MS SHILPI CHAUHAN (*Alternate*)
The Bombay Textile Research Association, Mumbai	SHRI V. K. PATIL
The Synthetics & Art Silk Mills Research Association, Mumbai	DR MANISHA MATHUR SHRI RAVI SINGH (*Alternate*)
BIS Directorate General	SHRI A. K. BERA, SCIENTIST 'F' AND HEAD (TXD) [REPRESENTING DIRECTOR GENERAL (*Ex-officio*)]

Member Secretary

SHRI DHARMBEER
SCIENTIST 'C' (TXD), BIS

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This Indian Standard has been developed from Doc No.: TXD 36 (14827).

Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

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Published by BIS, New Delhi